IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

Jeanette Perez Maceira, et al., *Plaintiffs*, v. Customed, Inc. et al., *Defendants*.	Case No. 3:23-cv-1445

Balchem Corporation's Motion To Dismiss Plaintiffs' Complaint Under Federal Rule of Civil Procedure 12(b)(6)

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Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Balchem Corporation ("Balchem") files this motion to dismiss Plaintiffs' Complaint for failure to state a claim.

Introduction

Plaintiffs' Complaint against Balchem fails to plead viable claims and should be dismissed with prejudice. Plaintiffs erroneously assert that Balchem is a manufacturer of ethylene oxide ("EtO"). But Balchem is only a distributor of EtO. Complaint at 2; 8 ¶ 27, ECF No. 1 ("Compl."). Balchem is not a medical sterilizer, does not own or operate sterilization facilities in Puerto Rico, and does not emit EtO. Compl. at 2; 4 ¶ 9. Plaintiffs' improperly pleaded claims in the Complaint alleging potential injuries and damages from the alleged emissions of EtO from the facilities of Customed, Inc.; Medtronic PR, Inc.; Edward LifeSciences Technology Sarl; and Steri-Tech, Inc. (collectively "Sterilizer Defendants") (**Counts I, II, III, and VIII**) do not apply to Balchem.[1]

The Court can dismiss Plaintiffs' product liability claims against Balchem on the pleadings. Plaintiffs allege that, in their judgment, EtO is a defectively designed product that should not be used for medical sterilization (**Counts IV, VI, and VII**). But Plaintiffs cannot dispute that EtO is critical for medical sterilization in the United States and that EtO cannot be redesigned. EtO is simply EtO. It is an organic compound that cannot be redesigned into a different sterilant. Plaintiffs also fail to allege that the warnings Balchem provided with EtO were deficient (**Count V**). While the Court should take notice of Balchem's EPA-approved EtO label and note other warnings to Sterilizer Defendants incorporated by reference in the Complaint, the Court need not rely on them in resolving Plaintiffs' failure to warn claim at this stage of the case. Plaintiffs do not have a plausible failure to warn claim against Balchem

[1] **Count IX** of the Complaint for Restitution-Unjust Enrichment is not properly pleaded against any of the Defendants. Plaintiffs also have failed to plead class action allegations against Defendants, which Balchem will address at a later time if Plaintiffs' Complaint survives this Motion. Compl. at 12–13 ¶¶ 66–72.

because they admit that the Sterilizer Defendants were fully aware of the risks and hazards associated with EtO at the time they allegedly emitted it from their facilities. Compl. at 3 ¶¶ 2, 6; 10 ¶ 33. Plaintiffs do not allege that Balchem had any duty to directly warn Plaintiffs. Compl. at 21 ¶¶ 107–08. Nor could they plausibly make such allegations.

Plaintiffs' Complaint relies upon a recent United States Environmental Protection Agency ("EPA") review of EtO that contradicts their product liability claims in this lawsuit. Compl. at 9 ¶ 29 n.6.[2] EPA recognizes that EtO is "highly valuable," "critical," that it "provides extensive benefits to public health," and "there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment." *Id*. EPA further concludes that "if commercial sterilization and healthcare facilities no longer had access to EtO to sterilize medical devices, the result would likely be a disruption to the medical device supply chain, which could in turn result in a nationwide public health crisis." *Id.* at 69. Balchem's conduct in distributing EtO under the auspices of EPA and other federal and state regulators is not merely legal; it is essential to ensuring the continued availability of sterilized medical equipment in Puerto Rico and the rest of the United States. For these reasons and those addressed further below, Balchem respectfully submits that the claims against it should be immediately dismissed.

Background

I. EtO Is Highly Regulated by Several Government Agencies

A. Balchem Distributes an EPA Approved and Labeled Product

The allegations in this case against Balchem are based on Plaintiffs' misconception that Balchem "manufactured" EtO. Compl. at 2. While Plaintiffs' error is not relevant for purposes of deciding this Motion, Balchem has never manufactured EtO. Balchem repackages EtO and

[2] U.S. EPA, *Ethylene Oxide, Proposed Interim Registration Review Decision*, No. EPA-HQ-OPP-2013-0244 (March 2023), at 3, 28 & 69, https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf (hereinafter "Interim Registration Review") (incorporated by reference).

distributes it to third parties for various uses including medical sterilization. Compl. at 8 ¶ 27.[3] Balchem's EPA-registered product is 100% ethylene oxide (CAS NO. 75-21-8). As is readily apparent on its label, the product is not a mixture of gases from which EtO could be reduced or removed. Compl. at 19 ¶¶ 93–95; EtO 100% Label.

The EtO distributed by Balchem is highly regulated by EPA, the Puerto Rico Department of Agriculture, U.S. Food & Drug Administration ("FDA"), and the Occupational Safety and Health Administration ("OSHA"). EtO is registered by Balchem as a pesticide (EPA Reg. No. 36736) and approved for use as a medical sterilant by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Compl. at 9 ¶ 29. Balchem also maintains a pesticide registration with the Puerto Rico Department of Agriculture (P.R. Reg. No. 03845-1).

Prior to registration of EtO as a pesticide, EPA required submission of extensive scientific data on EtO, information on its proposed uses, potential toxicity, and labeling. Compl. at 9 ¶ 30, n.7.[4] As part of the pesticide registration process, EPA develops risk assessments, including human health risks ranging "from short-term toxicity to long-term effects such as cancer and reproductive system disorders." *About Pesticide Registration.* EPA also closely regulates all labeling of pesticide products, including EtO:

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[3] *See* Exhibit 1, Ethylene Oxide 100%, U.S. EPA: ARC Specialty Products – Balchem Corp., April 8, 2013, (hereinafter "EtO 100% Label"). The Court may take judicial notice of Balchem's product label and ethylene oxide registration. "Courts addressing motions to dismiss product-labeling claims routinely take judicial notice of images of the product packaging." *Sandoval v. PharmaCare US, Inc.*, 145 F. Supp. 3d 986, 992 (S.D. Cal. 2015). In assessing a motion to dismiss, a court "may augment these facts and inferences [in the complaint] with data points gleaned from documents incorporated by reference into the complaint, matters of public record, and facts susceptible to judicial notice." *A.G. ex rel Maddox v. Elsevir, Inc.*, 732 F.3d 77, 80 (1st Cir. 2013).

[4] *How to Register a Pesticide*, U.S. EPA, https://www.epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process (last updated March 2, 2023) (incorporated by reference); *see also About Pesticide Registration*, U.S. EPA, https://www.epa.gov/pesticide-registration/about-pesticide-registration (last updated Jan. 25, 2023) ("In evaluating a pesticide registration application, we assess a wide variety of potential human health and environmental effects associated with use of the product. The company that wants to produce the pesticide must provide data from studies that comply with our testing guidelines."); *Gent v. CUNA Mut. Ins.,* 611 F.3d 79, 84 n.5 (1st Cir. 2010) (judicial notice may be taken of information from an official government website, as such facts are "not subject to reasonable dispute") (quoting Federal Rule of Evidence 201(b)).

> We [U.S. EPA] review pesticide product labels as part of the licensing/registration process and must approve all label language before a pesticide can be sold or distributed in the United States. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. It is a violation of federal law to use a pesticide in a manner inconsistent with its labeling. The courts consider a label to be a legal document. In addition, following labeling instructions carefully and precisely is necessary to ensure safe and effective use.

Id. EPA reviewed and approved all language on Balchem's EtO product label. Compl. at 9 ¶ 29.

As required by law, Balchem's product label is affixed to all EtO distributed in the United States, including Puerto Rico. *See* EtO 100% Label. The label includes numerous warnings regarding human health, cancer, and reproductive dangers. *Id*. The label states: "Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047)." *Id.* The label also provides information regarding product hazards and detailed directions for use.[5] In addition to the label, Balchem's EtO is accompanied by a Safety Data Sheet ("SDS"), which contains an additional list of EtO hazards and information regarding safe handling of the product.[6] Compl. at 8 ¶ 27. The SDS provides that airborne levels of EtO must be controlled and states that facility "[e]mission controls must be in compliance with Federal, State and local regulations." SDS at 7. The SDS includes detailed information on cancer risks from EtO. *Id*. at 10–13. Balchem also periodically provides product stewardship presentations to some of its medical sterilizer customers regarding the "safe use and handling" of EtO. Compl. at 9 ¶ 28; ECF No. 37 at 6 (referred to by Plaintiffs as "training").

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[5] EtO 100% Label ("It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 29 CFR 1910.1047. This product may be used only in facilities that meet the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047) . . . . This product may be used only by persons who have been trained in accordance with the Ethylene Oxide Standard (29 CFR 1910.1047). When used to sterilize health care items, this product must be used in non-portable (commercial) ethylene oxide gas sterilizers that have FDA clearance.").

[6] *See* Exhibit 2, Ethylene Oxide Safety Data Sheet. New Hampton, NY: ARC Specialty Products c/o Balchem Corp., at 5 (hereinafter "SDS") ("DANGER! Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly Reactive. Harmful or fatal if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.") (incorporated by reference).

B. The Use of EtO by Medical Sterilizers Is Highly Regulated

In addition to significant regulation of EtO as a pesticide, EPA closely regulates the use and emissions of EtO at sterilization facilities in the United States under the Clean Air Act. EtO emissions are regulated as hazardous air pollutants under Section 112 of the Clean Air Act. 42 U.S.C. § 7412 (2024). On April 11, 2023, EPA proposed amendments to the National Emissions Standards for Hazardous Air Pollutants ("NESHAPs") at commercial EtO sterilization facilities.[7] EPA's proposed rule for EtO emissions applies to 86 commercial sterilization facilities.[8] Notably, in announcing the draft Clean Air Act rule for EtO, EPA indicated it had **no plans to ban** the use of EtO and identified the critical importance of EtO for continued use in medical sterilization: "Medical sterilization is a **critical function** that ensures a safe supply of medical devices for patients and hospitals. EPA is proposing an expedited timeline for facilities to meet emissions requirements in order to reduce risks to communities located near these facilities while continuing to provide important sterilization services." EPA Fact Sheet at 1 (emphasis added).

EtO is also closely regulated by the FDA. Compl. at 9 ¶ 29 n.6.[9] The FDA standards for EtO require strict compliance from medical sterilization facilities. In its own words, the FDA has a "robust standards program" for sterilization of medical devices.[10] Medical sterilizers must obtain FDA approval of their sterilization method prior to entering the sterilization market. FDA recognizes two voluntary standards that "describe how to develop, validate, and control ethylene oxide sterilization processes for medical devices and the acceptable levels of residual ethylene

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[7] *See* NESHAPs: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 88 Fed. Reg. 22,790 (April 13, 2023).

[8] *See* EPA Proposes to Strengthen Clean Air Act Standards for Ethylene Oxide from Commercial Sterilization Facilities: Fact Sheet, U.S. EPA, at 2, https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet%20Proposal%20to%20Address%20EtO%20Risks%20from%20Commercial%20Sterilizers.pdf (last visited January 3, 2024) (hereinafter "EPA Fact Sheet").

[9] Interim Registration Review, at 12–13 (incorporated by reference).

[10] *Sterilization for Medical Devices*, U.S. FDA (Jan. 8, 2024), https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#how.

oxide and ethylene chlorohydrin left on a device after it has undergone ethylene oxide sterilization." *Id.* Any variance from these standards requires FDA approval. *Id.* The FDA closely monitors the use of EtO because of concerns regarding potential shortages of medical devices.[11]

OSHA also has strict regulations that apply to all occupational exposures to EtO, including at commercial sterilization facilities. 29 C.F.R. § 1910.1047 (2024). The OSHA guidelines require "chemical manufacturers, importers, distributors, and employers" to comply with the Hazard Communication Standard for EtO, including providing employee access to labels, safety data sheets, and training. 29 C.F.R. § 1910.1200 (2024). Medical sterilization facilities using EtO are subject to inspections, fines and penalties, and even involuntary closure by EPA, Puerto Rico, FDA, and OSHA if they fail to comply with federal regulations relating to the use and emission of EtO from their facilities.[12]

II. EtO Is Naturally Occurring and There Are Numerous Industrial Sources

Less than one percent of EtO is used for sterilization.[13] Most industrially manufactured EtO is used as an intermediate in other chemical manufacturing processes. *Id.*; Compl. at 8 ¶ 26. EtO is also naturally occurring: "Ethylene oxide is produced in the body from oxidation of ethylene, and biological processes producing endogenous ethylene have been identified, such as lipid peroxidation, methionine and heme oxidation, and metabolic activity of intestinal bacteria."

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[11] *See Ethylene Oxide Sterilization Updates*, U.S. FDA (June 2, 2021), https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates ("The FDA is closely monitoring the supply chain effects of closures and potential closures of certain facilities that use ethylene oxide to sterilize medical devices prior to their use. The Agency is concerned about the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care.").

[12] *See, e.g.*, *How We Monitor Compliance*, U.S. EPA, https://www.epa.gov/compliance/how-we-monitor-compliance (last updated June 1, 2023) (describing inspections and other compliance procedures); 29 C.F.R. § 1903.3 (2024) (OSHA Authority for Inspection); 29 C.F.R. § 1903.15 (2024) (OSHA penalties).

[13] U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Ethylene Oxide,* at 99 (August 2022), https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf (hereinafter "ATSDR Report").

ATSDR Report, at 2. EtO also forms naturally from the degradation of plants and "can also emanate from water-logged soil, manure, and sewage sludge." *Id.* at 100. There are numerous potential sources of exposure to EtO in the urban environment, notably including tobacco smoke and automobile exhaust. *Id.* at 100 & 106.

III. EtO Is Critical for Sterilization of Medical Devices in the United States

EtO is used on over 20 billion health care products per year in the United States. Compl. at 8 ¶ 25. EtO is used on approximately 50% of all sterilized medical devices, including an estimated 95% of all surgical kits. Compl. at 9 ¶ 29 n.6.[14] "EtO is highly valuable in the industrial sterilization setting – or any setting that has the objective of destroying, inactivating, or physically removing all microorganisms to meet defined sterility assurance standards – because it is a penetrative gas that has a high throughput capacity, is effective at a wide range of temperatures, and is compatible with a broad range of materials." *Id.* EPA acknowledges that there are no "viable alternatives" to EtO for certain medical devices.[15] According to EPA and FDA, the "absence of EtO for use on medical devices and equipment would cause widespread disruption to the availability of sterile medical devices including feeding tubes used in neonatal intensive care units, drug-eluting cardiac stents, catheters, shunts, and other implantable devices."[16] While there are efforts to reduce EtO emissions from sterilizer facilities, EPA and other agencies recognize its vital importance and have no plans to ban it. *Id.*

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[14] Interim Registration Review, at 28 (incorporated by reference).

[15] *Id.* ("Presently, there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment because gamma irradiation and e-beam irradiation, the next most commonly employed methods for medical device sterilization, cannot be used on certain materials.").

[16] *Id.* ("Other technologies (e.g., hydrogen peroxide, chlorine dioxide, vaporized peracetic acid) are limited due to issues with material compatibility, scalability, and because they lack accepted validation measures for sterility assurance."); FDA Statement, Norman E. Sharpless, MD, Acting Commissioner of Food and Drugs, Statement on concerns with medical device availability due to certain sterilization facility closures (Oct. 25, 2019), https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures.

Legal Standard

The United States Supreme Court has directed that a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). The facts alleged in the complaint "must be enough to raise a right to relief above the speculative level . . . ." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2005); *Lozada v. Dejoy*, No. 20-1674, 2023 WL 2433860, at *8 (D.P.R. Mar. 9, 2023) (quotation omitted). A court should grant a motion to dismiss when the complaint provides "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," or the complaint "tenders naked assertions devoid of further factual enhancement." *Iqbal*, 556 U.S. at 678 (citations and quotations omitted). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Id*. "A plaintiff is not entitled to 'proceed perforce' by virtue of allegations that merely parrot the elements of the cause of action." *Betancourt-Colon v. Kimco PR Mgmt. Corp.*, No. CV 22-1055 (DRD), 2023 WL 6393065, at *3 (D.P.R. Sept. 30, 2023) (citation omitted). "When allegations, though disguised as factual, are so threadbare that they omit any meaningful factual content, we will treat them as what they are: naked conclusions." *Maddox*, 732 F.3d at 81.

Argument

I. The Complaint Should Be Dismissed for Failure to State a Claim Against Balchem

A. Plaintiffs' Negligence Claim Should Be Dismissed

Plaintiffs have not alleged a viable claim for negligence against Balchem (Negligence (**Count I**)). Plaintiffs' negligence claim includes allegations regarding emissions of EtO from medical sterilizers' facilities in Puerto Rico that have absolutely no bearing on Balchem. Compl. at 15 ¶¶ 74–76. None of the allegations regarding Sterilizer Defendants' alleged duties or breach

of their duties in Count I have anything to do with Balchem's alleged manufacture or actual distribution of EtO.

Article 1536 of the Civil Code of 2020[17] permits the recovery of damages upon a showing that a defendant "as a result of fault or negligence[] cause[d] damage to another." P.R. Laws Ann. tit. 31, § 10801; *see* Art. 1802 of the prior Civil Code of 1930, P.R. Laws Ann. tit. 31, § 5141 (equivalent language).[18] Thus, in order to plead a negligence claim, "the plaintiff must establish the following: (1) a duty requiring the defendant to conform to a certain standard of conduct; (2) a breach of that duty; (3) proof of damage; and (4) a causal connection between the damage and the tortious conduct." *Sanchez v. Seguros Triple S, Inc.*, 687 F. Supp. 2d 6, 9 (D.P.R. 2010).

Plaintiffs cannot establish that Balchem owed Plaintiffs a duty because Plaintiffs' sole allegation is that "[a]t all times relevant, Defendants owed a duty to Plaintiffs and the Class to **exercise reasonable care in the operation of their facilities, including the emission of EtO**." Compl. at 15 ¶ 74 (emphasis added). Balchem is not alleged to have ever owned or operated a facility in Puerto Rico. *Id.* at 2. Plaintiffs' negligence allegations against Balchem are therefore entirely misplaced. *See Lopez-Rivera v. Hosp. Auxilio Mutuo, Inc.*, 247 F. Supp. 3d 185, 189 (D.P.R. 2017) ("Even under the rules of notice pleading, the plaintiff must satisfy the requirement of providing not only fair notice of the nature of the claim, but also grounds on which the claim rests.").

[17] Although the Complaint relies on provisions of the Puerto Rico Civil Code of 2020, pursuant to Article 1815 of the Code, "[t]ort liability, both in its scope and nature, is determined by the law in effect at the time that the act or omission giving rise to such liability occurred." P.R. Laws Ann. tit. 31, § 11720. Moreover, "[i]f any acts or omissions occurred before the effective date of the [2020] Code and others occurred afterward, liability is governed by the previous legislation." *Id.* Since the allegations in this case include facts from before and after 2020, the Puerto Rico Civil Code of 1930 should govern, particularly if any differences arise in the applicable legal standard under the two Codes as to any of Plaintiffs' claims.

[18] Balchem has requested certified translations of all cited provisions of the Civil Code of 2020 and opinions of the Puerto Rico courts for which official translations are not yet available, in compliance with Local Civil Rule 5(c). The majority of those translations are submitted with this motion, and the remainder shall be submitted to the record as soon as they are provided to Balchem by the certified translator.

In addition to failing to plead that Balchem owed a duty to the Plaintiffs, Plaintiffs fail to plead that Balchem breached a duty. Plaintiffs identify seven different breaches of duty in the Complaint, but all involve the alleged conduct of the Sterilizer Defendants, not Balchem. Compl. at 15 ¶ 75; *Jimenez-Ruiz v. Spirit Airlines, Inc.*, 794 F. Supp. 2d 344, 351 (D.P.R. 2011) ("As a general rule, an individual is only liable for his own acts or omissions and only by exception is an individual liable for the acts or omissions of others. A third party can only be liable for the acts or omissions of others when clearly specified in the law.") (citations and quotations omitted). While Balchem did not proximately cause Plaintiffs' alleged injuries,[19] the Court need not even reach that issue because Plaintiffs do not plead that Balchem had a duty or breached a duty to Plaintiffs.

B. Plaintiffs' Gross Negligence Claim Should Be Dismissed

Plaintiffs' gross negligence claim (**Count II**) should be dismissed because "Puerto Rico tort law is governed by civil law and not by common law" and therefore "Puerto Rico courts do not recognize gross negligence or any other degrees of negligence found in common law." *Benito-Hernando v. Gavilanes*, 849 F. Supp. 136, 140 (D.P.R. 1994). "Puerto Rico tort law does not recognize a specific civil cause of action for intentional or grossly negligent acts." *Id.* Because gross negligence is not a viable cause of action, this claim should be dismissed.

C. Plaintiffs' Nuisance Claims Should Be Dismissed

The Court should dismiss Plaintiffs' nuisance claims (for Private Nuisance (**Count III**) and Public Nuisance (**Count VIII**)) against Balchem with prejudice because the claims are based

[19] *See Jiménez v. Pelegrina Espinet*, 12 P.R. Offic. Trans. 881, 887, 112 P.R. Dec. 700 (1982); Art. 1166 of the Civil Code of 2020, P.R. Laws Ann. tit. 31, § 9318 ("Apart from those cases expressly mentioned in the statute and those provided for in the obligation, no one can be held liable for events that were unforeseeable or which, although foreseeable, were unavoidable."); Art. 1058 of the Civil Code of 1930, P.R. Laws Ann. tit. 31, § 3022 (equivalent language).

on alleged emissions of EtO. Compl. ¶¶ 86–89. Balchem did not own or operate facilities in Puerto Rico or emit EtO. Compl. at 2.

The Puerto Rico Civil Code generally defines "nuisance" as "anything which is injurious to health, indecent, or offensive to the senses, or an obstruction to free use of property so as to interfere with the comfortable enjoyment of life or property, or that is a nuisance to the well-being of a neighborhood, or to a large number of persons . . . ." Art. 277 of the Code of Civil Procedure, P.R. Laws Ann. tit. 32, § 2761.

To obtain injunctive or compensatory relief based on a nuisance theory, a plaintiff must show that the defendant's activities and the way the defendant conducted those activities "exceed[ed] the bounds of reasonableness" and imposed an excessive burden on the plaintiff. *Casiano v. Lozada Torres*, 91 P.R. Dec. 488, 493, 91 P.R. 473, 478 (1964). The "measure of what is reasonable" will depend on "a series of factors" in light of the facts of the particular case, including without limitation: "the place where the challenged activity takes place, the nature, extension, utility and value of that [activity], the character of the damage allegedly suffered, and the nature of the right or the use affected by the alleged nuisance." *S.L.G. Flores Jiménez v. Colberg*, 173 P.R. Dec. 843, 856 (2008). Even if an activity is declared a nuisance, Puerto Rico courts have held that the availability of damages under Article 277 depends on the plaintiff establishing the elements of a traditional tort, including actual damage and causation. *See Martínez Romero v. Super Asphalt Pavement, Co.*, KLAN201701052, 2018 WL 3037397, at *10 (P.R. Ct. App. Apr. 23, 2018).

Plaintiffs cannot plausibly allege a claim for private or public nuisance against Balchem. *Maddox*, 732 F.3d at 81. Plaintiffs do not allege that Balchem owned or operated any facilities in Puerto Rico. Compl. at 2. Balchem therefore could not have caused the alleged emissions of EtO into the environment that Plaintiffs claim caused their injuries and damages. *See Scarlett &*

Assocs., Inc. v. Briarcliff Ctr. Partners, LLC, No. 1:05-cv-0145-CC, 2009 WL 3151089, at *15 (N.D. Ga. Sept. 30, 2009) ("The essential element of nuisance is control over the cause of the harm."). Accordingly, Plaintiffs' nuisance claims against Balchem should be dismissed with prejudice.

D. Plaintiffs' Design Defect Claims Should Be Dismissed

Plaintiffs' design defect claims (Strict Liability Design Defect (**Count IV**), Negligent Design Defect (**Count VI**), and Gross Negligent Design Defect (**Count VII**)) fail as a matter of law because Plaintiffs merely allege that EtO is "unreasonably dangerous" and do not identify a defective design. Compl. at 19 ¶ 93. Plaintiffs ignore indisputable facts about EtO. EtO is simply EtO. EtO cannot be redesigned into another chemical compound and still be used for sterilization.

The Puerto Rico Civil Code of 2020 recognizes a strict liability claim for "[p]eople who sell in the flow of commerce a product that by its design or manufacture is unreasonably dangerous." Art. 1542 of the Puerto Rico Civil Code of 2020, P.R. Laws Ann. tit. 31, § 10807. "A design defect is 'an imperfection occurring when the seller or distributor could have reduced or avoided a foreseeable risk of harm by adopting a reasonable alternative design, and when, as a result of not using the alternative, the product or property is not reasonably safe.'" *Garcia v. Hartford Fin. Servs. Grp., Inc.*, No. CV 18-2013 (JAG), 2022 WL 2836272, at *1 (D.P.R. June 1, 2022) (quoting *Defect*, Black's Law Dictionary (11th ed. 2019)). The scope of a design defect claim "does not extend to every conceivable risk, since the manufacturer is not an absolute insurer of all injuries that his product may produce." *Coquí Holdings, CRL v. Maderas 3C, LLC*, No. SJ2021CV01050, 2023 WL 5286421, at *8 (P.R. Ct. App. July 18, 2023).

Courts in Puerto Rico have recognized two standard tests for establishing a design defect, including the "consumer-expectancy" test and the "risk-benefit" test. *Hartford Fin. Servs. Grp.,*

Inc., 2022 WL 2836272, at *1. Under the consumer-expectancy test, the plaintiff must allege that "the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." *Collazo-Santiago v. Toyota Motor Corp.*, 149 F.3d 23, 25 (1st Cir. 1998) (citation omitted). Alternatively, under the risk-benefit test, the plaintiff must allege that "the product's design proximately caused his [or her] injury and the defendant fails to establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design." *Id.* at 25–26 (citation omitted).

The consumer-expectancy test does not apply to Plaintiffs' design defect claims because the "test 'cannot be the basis of liability in cases involving complex technical matters.'" *Alvarez-Cabrera v. Toyota Motor Sales, U.S.A., Inc.*, No. CV 17-2305 (RAM), 2020 WL 3620204, at *4 (D.P.R. July 2, 2020) (quoting *Quintana-Ruiz v. Hyundai Motor Corp.*, 303 F.3d 62, 77 (1st Cir. 2002)). The consumer-expectancy test is "reserved for cases in which the *everyday experience* of the product's users permit a conclusion that the product's designs violated *minimum* safety assumptions . . . . The District of Puerto Rico has abstained from using this test in a case involving such a seemingly simple product as an aircraft overhead bin." *Muñiz-Negrón v. Worthington Cylinder Corp.*, No. 17-1985 (RAM), 2021 WL 1199014, at *4 (D.P.R. Mar. 30, 2021) (citation omitted); *see also Fremaint v. Ford Motor Co.*, 258 F. Supp. 2d 24, 29 (D.P.R. 2003) (holding that consumer-expectancy test is inapplicable in a case "involving complex technical matters" because it "would impermissibly permit a jury to find liability on little more than intuition or whim").

Balchem's EtO is not sold to or used by ordinary consumers. Compl. at 8 ¶ 25; 9, ¶ 29 n.6.[20] It can only be used by trained employees at licensed commercial medical sterilizers. *Id.*; *see also* EtO 100% Label. Because the public and ordinary consumers cannot have expectations

[20] Interim Registration Review, at 12 (incorporated by reference).

regarding EtO's performance as a medical sterilant, the consumer-expectancy test does not apply to Plaintiffs' design defect claims. *See Muñiz-Negrón*, 2021 WL 1199014, at *4 (stating that "consumers would likely not have any specific expectations as to how safe propane cylinders should be") (citations and quotations omitted); *In re MBTE Prods. Liab. Litig.*, No. M21-88, 2015 WL 3763645, at *4–5 (S.D.N.Y. June 16, 2015) (declining to apply consumer-expectancy test to gasoline additive because courts should only use the "test when a consumer would . . . know what to expect, or . . . how safe the product could be made.") (citations and quotations omitted).

Plaintiffs also fail to plead viable design defect claims under the risk-benefit test. Under this test, a plaintiff must allege "that the product's design proximately caused his injuries." *Muñiz-Negrón*, 2021 WL 1199014, at *5. In evaluating a design defect claim under the risk-benefit test, courts consider factors including: "the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the . . . feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design." *Carballo-Rodriguez v. Clark Equip. Co.*, 147 F. Supp. 2d 66, 72 (D.P.R. 2001) (citation omitted). Plaintiffs have not—and even with an amendment could not—plead viable design defect claims.

Plaintiffs allege that "Defendants' EtO mixtures and EtO-containing products as described herein constituted an unreasonably dangerous design of such products in that **they contained EtO** . . . ." Compl. at 19 ¶ 93 (emphasis added). **The product at issue, in fact, is 100% EtO**.[21] The product cannot be redesigned to omit EtO because the product is EtO. "Puerto Rico courts have explained that 'an important part of the risk-utility test is the question of

[21] *See* EtO 100% Label ("Active Ingredient: Ethylene Oxide…100%"). Any change to the chemical structure of EtO would result in a completely different organic chemical rather than a different (much less, a safer or equally effective) sterilization product.

whether there is a safer alternate design which is mechanically feasible.'" *See Muñiz-Negrón*, 2021 WL 1199014, at *5 (quoting *Fremaint*, 258 F. Supp. 2d at 30). There is no feasible way to redesign the EtO compound C_2H_4O and still have the same product.

Plaintiffs plead that a variety of alternatives could be used for medical sterilization instead of EtO, including "mineral oils, silicone fluids, vegetable oils, and nonfluid insulating chemicals," but miss the point. Compl. at 20 ¶ 98. Under the applicable legal standard, even if substitutes could be used for EtO sterilization, none of these chemicals is an alternative **design** for EtO. *See id*. Moreover, Plaintiffs' position that EtO is a defective product that can be replaced by other "available" alternatives contradicts the very authorities they cite in their own Complaint. Compl. at 9, ¶ 29 n.6 (citing EPA's Interim Registration Review, at 28, which states "**there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment**") (emphasis added). Plaintiffs' failure to identify a design defect in EtO requires dismissal of this claim. *Ayala v. Kia Motor Corp.*, 633 F. Supp. 3d 555, 574 (D.P.R. 2022) (dismissing "bald allegations" of design defect where plaintiff did not identify a specific defect).

When a plaintiff attempts to allege a design defect based on the product itself rather than the specific design of the product, courts do not recognize a viable design defect claim. As one court explained, "[t]his is akin to alleging a design defect in champagne by arguing that the manufacturer should have made sparkling cider instead. The challenge is to the product itself, not to its specific design." *City of Philadelphia v. Lead Indus. Ass'n*, No. CIV. A. 90-7064, 1992 WL 98482, at *3 (E.D. Pa. Apr. 23, 1992), *aff'd sub nom. City of Philadelphia v. Lead Indus. Ass'n, Inc.*, 994 F.2d 112 (3d Cir. 1993). "[S]ome ingredients cannot be eliminated from a design without eliminating the product itself. When the ingredient cannot be designed out of the product, the Restatement (Second) instructs . . . the proper claim is not design defect." *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674, 687 (Wis. 2009).

Courts do not recognize design defect claims, like those here, which are simply attempts to ban the use of a product. *See S.F. v. Archer Daniels Midland Co*., 594 F. App'x 11, 12 (2d Cir. 2014) ("[A] design-defect claim will not stand if the only alternative is an outright ban."); *Town of Lexington v. Pharmacia Corp*., 133 F. Supp. 3d 258, 270 (D. Mass. 2015) ("A plaintiff does not meet its burden of demonstrating a design defect by alleging that an entire class of products is inherently dangerous. Courts do not impose liability based on a conclusion that an entire product category should not have been distributed in the first instance.").

Plaintiffs' design defect claims (**Count IV**, **Count VI**, and **Count VII**[22]) should be dismissed with prejudice. Plaintiffs have not alleged plausible claims for design defect because Balchem's 100% EtO product is a basic chemical compound, approved for use as a medical sterilant, which cannot be redesigned to omit its only ingredient.

E. Plaintiffs' Failure to Warn Claim Should Be Dismissed

Plaintiffs' failure to warn claim (Failure to Warn and Instruct (**Count V**)) against Balchem should be dismissed with prejudice. Plaintiffs allege failure to warn under Article 1541 of the Puerto Rico Civil Code of 2020, P.R. Laws Ann. tit. 31, § 10806, which only creates a cause of action against: "(d) owners or those in possession of property which constitutes a nuisance, as defined by law, for damages resulting from such condition; or for the storage of substances that threaten the safety of others." Plaintiffs fail to state a claim for "failure to warn" against Balchem because Article 1541 of the Civil Code does not apply to Balchem. By Plaintiffs' own admission, Balchem is not an owner or possessor of any of the Sterilizer Defendants' facilities from which EtO was allegedly "used on, stored on, and emitted from." Compl. at 2; 4 ¶ 9. Even amendment of the Complaint could not remedy this pleading defect.

[22] Plaintiffs' Gross Negligence Design Defect claim (**Count VII**) should also be dismissed because Puerto Rico does not recognize claims for gross negligence. *See Benito-Hernando*, 849 F. Supp. at 140.

Further, Plaintiffs fail to state a failure to warn claim under any other potentially applicable Puerto Rico law. Courts applying Puerto Rico law have held that a plaintiff who alleges a failure to warn claim must plead each of the following: "(1) the manufacturer knew, or should have known of the risk inherent in the product; (2) there were no warnings or instructions, or those provided were inadequate; (3) the absence of warnings made the product inherently dangerous; [and] (4) the absence of adequate warnings or instructions was the proximate cause of plaintiff's injury." *Cruz-Vargas v. R.J. Reynolds Tobacco Co*., 348 F.3d 271, 276 (1st Cir. 2003). In order to succeed with a failure to warn claim, a plaintiff "must adduce evidence that the absence of warnings made the product inherently dangerous." *Muñiz-Negrón*, 2021 WL 1199014, at *4–5 (quoting *Hernandez Denziac v. Kia Motors Corp.*, 323 F. Supp.3d 277, 286 (D.P.R. 2018)). If a plaintiff's injuries or damages would have occurred regardless of the warning, the plaintiff cannot succeed with the claim. *See Santos-Rodriguez v. Seastar Sols.*, 858 F.3d 695, 698 (1st Cir. 2017) (upholding dismissal of failure to warn claim where there was no causal connection between alleged failure to warn and plaintiff's alleged injury).

Plaintiffs effectively plead themselves out of a failure to warn claim against Balchem on causation grounds because they admit in the Complaint that the Sterilizer Defendants knew or should have known of the potential dangers of EtO when it was allegedly emitted from their facilities in Puerto Rico. Compl. at 3 ¶ 6 ("At all relevant times, the Defendants knew, or should have known, that EtO is dangerous, toxic, carcinogenic, mutagenic, and causes various illnesses . . . . its carcinogenic and DNA-damaging effects have been widely studied and known since the 1940s and **definitively known** to Defendants **since at least 1984**. Notwithstanding, Defendants chose to operate their business [sic] and emit EtO . . . .") (emphasis added). Put simply, any alleged failure by Balchem to provide adequate warnings to the Sterilizer Defendants is immaterial in this case because Plaintiffs admit that Sterilizer Defendants **already knew** of

EtO's potential dangers. *See Santos-Rodriguez*, 858 F.3d at 698; *see also Taylor v. Am. Chemistry Council*, 576 F.3d 16, 24 (1st Cir. 2009) (holding that "there is no duty to warn an 'end user' of a product's latent characteristics or dangers when the user knows or reasonably should know of those dangers"); *SUEZ Water New York Inc. v. E.I du Pont de Nemours & Co.*, 578 F. Supp. 3d 511, 563 (S.D.N.Y. 2022) (dismissing failure to warn claim against chemical manufacturer where plaintiff failed to allege warning "would have ameliorated the harm"). Plaintiffs cannot have it both ways and allege that Balchem somehow failed to adequately warn the Sterilizer Defendants of the risks of EtO emissions, and also allege those same defendants were aware of the risks of EtO and "disregarded EtO's harmful properties and continued to release it into the surrounding communities." Compl. at 3 ¶ 2.

Plaintiffs also fail to allege, nor could they plausibly allege, that Balchem had a duty to directly warn Plaintiffs regarding Sterilizer Defendants' alleged emissions of EtO. Compl. ¶¶ 107–09. *See Groll v. Shell Oil Co.*, 148 Cal. App. 3d 444, 449–51 (Cal. Ct. App. 1983) (holding that manufacturer of lantern fuel was only responsible for providing adequate warnings to distributor); *see also Rodriguez v. Torres*, No. 11-1602(MEL), 2015 WL 1138256, at *10, 13 (D.P.R. Mar. 13, 2015) (applying principles in *Groll* under Puerto Rico law); *Walker v. Stauffer Chem. Corp.*, 19 Cal. App. 3d 669, 674 (Cal. Ct. App. 1971) (holding that manufacturer had no general duty to warn public about dangers of sulfuric acid). Balchem could not have plausibly warned third parties regarding EtO emissions from sterilization facilities. That is especially true where Plaintiffs allege this group of third parties includes as much as 13% of the neighborhoods of Puerto Rico and over 172,000 people. Compl. at 1; 13 ¶ 67; *Reichwaldt v. Gen. Motors LLC*, 304 F. Supp. 3d 1312, 1317 (N.D. Ga. 2018) (holding car manufacturer had no duty to warn third parties where duty could not reasonably be fulfilled).

Even if Plaintiffs had not conceded that Sterilizer Defendants were already on notice of the potential dangers of EtO, Plaintiffs still fail to plausibly allege that the warnings Balchem provided to the Sterilizer Defendants were inadequate. Compl. at 21 ¶¶ 105–11. Plaintiffs' failure to warn claim faces a heavy burden because Balchem distributes EtO with a label and Safety Data Sheet ("SDS") that must comply with EPA and OSHA regulatory requirements. Under FIFRA regulations, Balchem first submitted its EtO label to EPA and obtained EPA's pre-approval prior to distributing EtO on the market. *See supra* at 11; 40 C.F.R. § 156.10 (2024) ("Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part."); EtO 100% Label. If Balchem sought to amend its label to supplement any of its current warnings, any such label amendments would require EPA approval under federal law. *Id.*[23] And even if the Court were to order Balchem to supplement the label, Balchem would still have to get those label amendments approved by EPA. Whether EPA would approve any label amendment is ultimately beyond Balchem's (and even the Court's) control.

Finally, contrary to Plaintiffs' allegations that Balchem somehow failed to provide a warning that EtO is potentially dangerous, toxic, and/or carcinogenic (Compl. at 21 ¶¶ 105–7), Balchem's EtO label states: "DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD." EtO 100% Label. *See Salvio v. Amgen Inc.,* No. 2:11–cv–00553, 2012 WL 517446, at *6 (W.D. Pa. Feb. 15, 2012) (dismissing failure to warn claim because the "warning provided by Defendants advised Decedent's prescribing physicians of the very injury that occurred"); *see also Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 576–77 (E.D.N.Y. 2012) (same). The label further instructs that all steps must be taken by those handling EtO to comply with the law and prevent human exposures and ambient releases of EtO. EtO 100% Label. The label states: "This product

[23] *See also Pesticide Registration Manual: Chapter 6 – Amending a Registered Pesticide Product*, U.S. EPA, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide (last updated June 26, 2023) ("Almost all modifications to the composition, labeling, or packaging of a registered product must be submitted to EPA with an application for amended registration.").

may be used only in facilities that meet the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047)." *Id.*

While Plaintiffs appear to ignore the warnings on Balchem's label in the Complaint, they acknowledge that the SDS for EtO includes warnings that EtO is a "[c]ancer and reproductive hazard." Compl. at 8–9 ¶ 27. The SDS also provides that the medical sterilizers' "[e]mission controls must be in compliance with Federal, State and local regulations." SDS at 7. The SDS provides that all human and airborne exposures to EtO must be avoided and those using EtO must comply with all applicable laws regulating EtO. *See Torres v. Nat'l Starch & Chem. Corp*., 896 F. Supp. 71, 74–75 (D.P.R. 1995) (holding that manufacturer provided adequate warning where it supplied company with OSHA warnings for chemicals). Plaintiffs cannot plausibly claim that these warnings were insufficient.

F. Plaintiffs' Restitution Claim Should Be Dismissed

Plaintiffs' restitution claim (**Count IX**) should be dismissed with prejudice. There are five elements required to state a restitution or unjust enrichment claim under Puerto Rico law: (1) existence of an enrichment; (2) a correlative loss (impoverishment); (3) nexus between the loss and the enrichment; (4) lack of cause to justify the enrichment; and (5) absence of a legal precept excluding application of the enrichment without cause doctrine. *See Ortiz Andújar v. Commonwealth*, 22 P.R. Offic. Trans. 774, 780, 122 P.R. Dec. 817, 823 (1988). These elements were incorporated in Article 1526 of the Civil Code of 2020, P.R. Laws Ann. tit. 31, § 10771 ("Should a person, without just cause, enrich themselves at the expense of another, such person will be obligated to indemnify them for the correlative wealth reduction to the extent of the person's enrichment, regardless of whether it results from obtaining an advantage or from the avoidance of a loss."). Plaintiffs do not state an unjust enrichment claim.

First, Plaintiffs fail to state the elements of an unjust enrichment claim. Plaintiffs' cursory allegations, *see* Compl. at 24 ¶¶ 129–32, fail to include the five elements required to state a claim under Puerto Rico law for unjust enrichment. The Complaint includes no recitation of the elements of the claim, much less facts supporting the elements of the claim. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Lopez-Rivera*, 247 F. Supp. 3d at 187 (citation omitted). Plaintiffs' factual allegations related to their unjust enrichment claim are conclusory. *See Solano-Moreta v. First Transit of PR, Inc.*, 964 F. Supp. 2d 214, 215 (D.P.R. 2013) (noting that conclusory factual allegations are discarded in analyzing if plaintiff has stated a plausible claim).

Second, Plaintiffs' decision to plead other tort claims precludes them from pleading an unjust enrichment claim. An unjust enrichment claim is not available in Puerto Rico whenever another cause of action based in contract or the general tort statute is also pled. *See, e.g.*, *Ocaso, S.A., Compañía De Seguros y Reaseguros v. P.R. Mar. Shipping Auth.*, 915 F. Supp. 1244, 1263 n.15 (D.P.R. 1996) (dismissing unjust enrichment claim where, "[d]efendants' allegedly fraudulent conduct would allow for a claim sounding in tort under art. 1802 of the P.R. Civil Code," despite time-bar on tort action). For these reasons, Plaintiffs' unjust enrichment claim should be dismissed.

II. Plaintiffs' Claims Are Time-Barred

Plaintiffs' claims are time-barred because Plaintiffs' alleged injuries occurred more than one year prior to filing and Plaintiffs do not plead any applicable exception to the statute of limitations. Because Plaintiffs' claims sound in tort, Puerto Rico's one-year statute of limitations "for general tort claims" applies. *Torres v. Hosp. San Cristobal*, 831 F. Supp. 2d 540, 543–44 (D.P.R. 2011); Art. 1204 of the Civil Code of 2020, P.R. Laws Ann. tit. 31, § 9496 (providing statute of limitations for claims sounding in tort under Puerto Rico law is one year "from the

moment the aggrieved person has knowledge of the existence of the damage and who caused it"); Art. 1868 of the Civil Code of 1930, P.R. Laws Ann. tit. 31, § 5298 (equivalent language). "[W]hen a tort claim is filed more than one year after the injury was caused, the plaintiff bears the burden of proving the timeliness of his claim as well as the lack of knowledge to assert it within the statutory period." *Torres*, 831 F. Supp. 2d at 544.

Plaintiffs do not allege why their claims could not have been brought years ago. "[A] plaintiff will be deemed to have 'knowledge' of the injury, for purposes of the statute of limitations, when she [he] has 'notice of the injury, plus notice of the person who caused it.'" *Bado-Santana v. Ford Motor Co.*, 283 F. Supp. 2d 520, 527 (D.P.R. 2003). "[T]he plaintiff need not 'know the exact name of the tortfeasor' to satisfy the requirement of knowledge of the person who caused the injury." *Kaiser v. Armstrong World Indus., Inc.*, 678 F. Supp. 29, 31 (D.P.R. 1987), *aff'd*, 872 F.2d 512 (1st Cir. 1989). Where, as here, the plaintiffs plead that the injury occurred years ago, the plaintiffs must—at a minimum—"plead *some* facts 'sufficient to give notice of [their] reliance on the discovery rule.'" *Quality Cleaning Prod. R.C., Inc. v. SCA Tissue N. Am., LLC*, 794 F.3d 200, 207 n.4 (1st Cir. 2015) (citation omitted). "The discovery rule is not a tool that plaintiffs may employ at-will to evade the statute of limitations. Instead, it is a doctrine with a limited reach, and its tolling benefit ends once a plaintiff discovers her injury. Therefore, a plaintiff cannot plausibly suggest that the discovery rule applies to her claim unless she **alleges the date on which she learned of her injury**." *In re Processed Egg Prod. Antitrust Litig.*, 931 F. Supp. 2d 654, 658 (E.D. Pa. 2013) (emphasis added); *see also Griggs v. Robinson Sec.*, No. 84 C 4679, 1985 WL 1163, at *5 (N.D. Ill. May 9, 1985) ("[I]t is the plaintiff's duty to affirmatively and particularly plead the date of discovery or face dismissal."). Plaintiffs fail to satisfy the minimum pleading requirements to state a viable claim.

A. Jeanette Perez Maceira

Plaintiffs plead that Ms. Maceira was "diagnosed with breast cancer in 2016," Compl. at 4 ¶ 6, which was approximately 7 years before the complaint was filed. At the latest, Ms. Maceira had knowledge of her injury when she was diagnosed. *See, e.g.*, *Kwasnik v. 160 Water St., Inc.*, No. 06 CIV. 1520 AKH, 2014 WL 7181171, at *1 (S.D.N.Y. Sept. 30, 2014) ("Discovery of the injury refers to 'the discovery of the manifestations or symptoms of the latent disease that the harmful substance produced.' . . . The plaintiff's injury need not be medically diagnosed for the statute to begin running."). Ms. Maceira has not alleged why she was unable to obtain knowledge of her claim, nor are there any allegations in the Complaint that state why she could not discover her injury in 2016 when she was diagnosed. Without pleading these facts, her claims are time-barred and must be dismissed.

B. Jose Luis Mateo Perez

Plaintiffs plead that Mr. Perez, the son of Ms. Maceira, "developed asthma in 1984," Compl. at 4 ¶ 7, nearly 40 years before the Complaint was filed. As a practical matter, the written records and witnesses required to provide relevant evidence on Mr. Perez's alleged injury may no longer be available. *See Ramos v. Roman*, 83 F. Supp. 2d 233, 252 (D.P.R. 2000) ("Just determinations of fact cannot be made when, because of the passage of time, the memories of witnesses have faded or evidence is lost."). Mr. Perez makes no attempt to plead why his alleged injury was not discovered in the last 40 years following his diagnosis. In the absence of these pleaded facts, his claims are time-barred.

C. Lillian M. Ortiz

Plaintiffs plead that Ms. Ortiz was diagnosed with thyroid cancer in 2022 after moving to Florida from Puerto Rico in 2007, Compl. at 4 ¶ 8, which means that the alleged cause of her injury must have occurred more than fifteen years before filing this case. Ms. Ortiz has failed to

plead sufficient facts to give Defendants notice of her reliance on the discovery rule. In the absence of these pleaded facts, her claims are time-barred and must be dismissed.

III. Plaintiffs Fail to State Plausible Claims as to Each Defendant

Plaintiffs' Complaint should be dismissed because Plaintiffs improperly employ "group pleading" to allege claims against multiple Defendants without identifying which claims concern each Defendant. The Court "must determine whether, *as to each defendant*, a plaintiff's pleadings are sufficient to state a claim on which relief can be granted." *Sanchez v. Pereira-Castillo*, 590 F.3d 31, 48 (1st Cir. 2009) (emphasis in original). "[W]hile a group pleading is not prohibited per se, the complaint must allege a plausible claim against each defendant." *Betancourt-Colon*, 2023 WL 6393065, at *5 (cleaned up). This means that "a complaint should at least set forth minimal facts as to who did what to whom, when, where, and why." *Id.* (citations and quotations omitted); *see also Figueroa Collazo v. Ferrovial Construcción PR, LLC*, No. 20-cv-1612 (DRD), 2021 WL 4482268, at *9 (D.P.R. Sept. 30, 2021) (holding that complaint that alleged minimal facts "as to the individual defendants" was insufficient to state a plausible claim).

Plaintiffs' Complaint is replete with allegations that treat Defendants as a monolithic group, instead of individual parties. For example, Plaintiffs allege—without differentiating between the six defendants named in the Complaint—that "**Defendants** have been emitting substantial quantities of EtO;" "Through their **industrial processes, Defendants** emit EtO into the air;" and "Plaintiffs . . . sustained damages arising out of Defendants' uniform wrongful conduct." Compl. at 3 ¶¶ 3–5; 14 ¶ 69 (emphasis added). But Defendants are not a monolithic group, as Plaintiffs concede elsewhere in the Complaint. Plaintiffs named six parties as Defendants and alleged that four of those defendants "operate medical sterilization facilities in Puerto Rico using ethylene oxide." Compl. at 2; 4 ¶ 9. Plaintiffs cannot plausibly allege that

Balchem has ever owned or operated a sterilization facility that emitted EtO. *See Sharma v. Terranova*, No. 20-1363, 2021 WL 4824116, at *1 (1st Cir. Mar. 8, 2021) (noting that a court does not abuse its discretion in dismissing a claim without leave to amend when plaintiff's "own factual allegations" mean that "amendment would have been futile"). Because Plaintiffs cannot amend the Complaint to plead viable claims against Balchem, the Complaint against Balchem should be dismissed with prejudice.

Conclusion

For the reasons set forth above, Balchem respectfully requests dismissal of the Complaint with prejudice.

Dated: January 19, 2024

Respectfully submitted,

/s/ Matthew D. Thurlow

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Certificate of Service

I hereby certify, that on January 19, 2024, this document was filed with the Court's CM/ECF system, which will simultaneously serve notice on all counsel of record to their registered email addresses.

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